

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1203
	:	
THIS DOCUMENT RELATES TO:	:	
	:	NO. 99-20593
SHEILA BROWN, et al.	:	
	:	
v.	:	
	:	
AMERICAN HOME PRODUCTS CORPORATION	:	
	:	
THIS DOCUMENT RELATES TO:	:	
	:	
Claimant: Linda O. Smith	:	
Claim No.: 183/00 8240345	:	2:15 MD 1203
	:	

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO**

**9388 )**

Bartle, J.

January 13, 2015

Linda O. Smith ("Ms. Smith") seeks benefits from the AHP Settlement Trust ("Trust") under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.<sup>1</sup> Before the court is the appeal of Ms. Smith from a September 23, 2014 determination by an arbitrator that although her claim was ripe for appeal she was not entitled to Matrix Compensation Benefits ("Matrix Benefits") because her claim documentation was incomplete.

1. Prior to March 11, 2002, Wyeth was American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

Under the Settlement Agreement, Matrix Benefits are awarded to compensate claimants for medical conditions caused by Pondimin® or Redux™ ("Diet Drugs").<sup>2</sup> A claimant, such as Ms. Smith, who seeks Matrix Benefits must submit documentation to the Trust to show that she suffers from a qualifying medical condition. Settlement Agreement § VI.C.4.a. She must also include a "Green Form" signed by an attesting physician. Id. § VI.C.2.c; see also id. § VI.C.4.a. If a claimant relies on the results of an echocardiogram to show that she suffers from a qualifying condition, the attesting physician must certify the results of the echocardiogram in the Green Form, and the claimant must provide a copy of the echocardiogram to the Trust. Id. § VI.C.2.f; see also id. § VI.C.4.a(2). A Claim for Matrix Benefits is not considered "complete" under the Settlement

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2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease. See Settlement Agreement, §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious valvular heart disease who took the drugs for 61 days or longer and who did not have any of the alternative causes of the disease that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious valvular heart disease who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their heart disease was caused solely by the use of these Diet Drugs.

Agreement until all documentation described in § VI.C.4.a of that Agreement along with a Green Form has been submitted to the Trust. Id. § VI.C.4.a. A claimant who is unable to obtain any of the documentation described in § VI.C.4.a may present to the Trust "other supporting documentation including but not limited to declarations of other Qualified Physician(s) under penalty of perjury setting forth opinion(s) to a reasonable degree of medical certainty" to demonstrate the claimant's entitlement to Matrix Benefits. Id. § VI.C.4.b.

Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"),<sup>3</sup> once a claim is completed in accordance with § VI.C of the Settlement Agreement, the Trust must refer it to audit, a process by which the claim is reviewed by an auditing cardiologist. Audit Rule 3. If a claim is denied without audit, including situations in which a claim is denied as incomplete, the claimant may appeal to the court. Audit Rule 18(e). Pursuant to the Settlement Agreement, the court must first refer the matter to arbitration. Settlement Agreement § VI.C.4.i. The Rules Governing Arbitration Process ("Arbitration Rules"), which were approved pursuant to Pretrial

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3. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in Pretrial Order No. 2807 (Mar. 26, 2003). The Audit Rules contained in Pretrial No. 2807 apply to Ms. Smith's claim.

Order No. 2153 (Sept. 12, 2001), state that an arbitrator must review factual determinations made by the Trust for clear error while legal conclusions must be reviewed de novo. Arbitration Rule 5. Any party may appeal the decision of the Arbitrator to the court. Settlement Agreement § VI.C.4.i. The decision of this court on appeal is final and binding. Id. § VI.C.4.1.

Ms. Smith initially sought severity level II Matrix Benefits. In support of that claim, Ms. Smith submitted a Green Form signed on March 7, 2003 by Dr. Tasneem Naqvi. On the basis of an echocardiogram performed on December 13, 2001 (the "December 2001 echocardiogram"), Dr. Naqvi represented that Ms. Smith suffered from moderate mitral regurgitation, left atrial enlargement, and New York Heart Association Functional Class III symptoms. Significantly, the December 2001 echocardiogram which served as the basis for Dr. Naqvi's findings did not bear Ms. Smith's name. Instead, it listed the identity of the patient depicted in the echocardiogram as "UNKNOWN." Nonetheless, Ms. Smith's initial claim was reviewed pursuant to the Seventh Amendment to the Settlement Agreement and was paid by the Seventh Amendment Fund Administrator.<sup>4</sup>

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4. Section IX.E of the Seventh Amendment to the Settlement Agreement provides that any determinations made by the Seventh Amendment Fund Administrator "shall have no preclusive or precedential effect of any kind on the Trust in the administration of claims for Matrix Compensation Benefits of Class Members who have exercised Seventh Amendment Opt-Outs or

Subsequent to Ms. Smith's initial claim, her mitral valve condition progressed to the point that she required surgery. As a result, she sought severity level III Matrix Benefits and forwarded a second Green Form in support of her claim. That Green Form was signed on March 6, 2011 by Dr. Leon J. Franzin. Dr. Franzin relied on the December 2001 echocardiogram, which identified the patient as "UNKNOWN," to reach the conclusion that Ms. Smith suffered from severe mitral regurgitation as well as left atrial enlargement, arrhythmias, an ejection fraction of 50-60%, surgery to repair or replace the mitral valve following Diet Drug use, and New York Heart Association Functional Class III symptoms. If confirmed at audit, these findings would justify a claim for Level III Matrix Benefits. In support of the Green Form signed by Dr. Franzin, Ms. Smith provided the Trust with the December 2001 echocardiogram.<sup>5</sup>

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of claims for Seventh Amendment Matrix Compensation Benefits." Accordingly, the reliance of the Seventh Amendment Fund Administrator on the December 2001 echocardiogram has no bearing on our analysis of the Trust's refusal to consider the same echocardiogram.

5. Section VI.C.2.f of the Settlement Agreement provides that a claimant who relies on the results of an echocardiogram to demonstrate her qualification for Matrix Benefits "must report the results of the Echocardiogram to the Trustees and/or Claims Administrator(s) in the form of ... a certification regarding the results of the Echocardiogram on the GREEN FORM." The claimant must also "provide the Trustees and/or Claims

On three occasions following Ms. Smith's submission of the December 2001 echocardiogram, the Trust informed her counsel by letter that her claim for severity level III Matrix Benefits was incomplete because the supporting echocardiogram identified the patient as "UNKNOWN." Apparently in response to these communications, Ms. Smith submitted evidence intended to demonstrate that the December 2001 echocardiogram was hers. This evidence included a declaration by Dr. Manoj R. Muttreja, a board-certified cardiologist, who described the method by which he was able to compare the December 2001 echocardiogram to later echocardiograms confirmed to be Ms. Smith's. Dr. Muttreja opined that the chordal structures depicted in the echocardiograms "are like a fingerprint that is unique to each person." Based on this comparison, Dr. Muttreja identified the heart imaged in the December 2001 echocardiogram as Ms. Smith's. Dr. Muttreja declared that his opinion was "based on a reasonable medical certainty."

Ms. Smith also tendered an additional declaration of Dr. Muttreja, entitled "Supplemental Declaration of Dr. Manoj R. Muttreja." In his supplemental declaration, Dr. Muttreja rejected the position of the Trust's counsel which challenged his findings. He reiterated that the patterns he saw in the

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Administrator(s) with a copy of the videotape or disk which reflects the results of the Echocardiogram."



December 2001 echocardiogram were "unique to Mrs. Linda O. Smith just as a fingerprint is unique to a specific person."

Dr. Muttreja concluded: "Given what I have described above, any well-trained echocardiographer would agree that the echocardiogram from December 13, 2001 was more likely than not from the same person as the other echocardiograms, and the echocardiogram did not show a heart belonging to someone else."

In addition to the two declarations of Dr. Muttreja, Ms. Smith supplied a declaration of board-certified cardiologist Paul W. Dlabal M.D., who likewise compared the December 2001 echocardiogram with a later echocardiogram of Ms. Smith's heart. Dr. Dlabal stated: "Without knowing the identity of the patient on 12/13/01, based upon the numerous similarities found on the two studies, it is my opinion that these two echocardiograms were performed on the same person." His opinion was "based on a reasonable medical certainty."

Ms. Smith further provided an affidavit from Deborah S. Kerr, her attorney at the law firm of Goldberg & Osborne. Ms. Kerr explained that it was her law firm's practice to have a client sign a contingent fee agreement on the same day that the client underwent an echocardiogram. She attached Ms. Smith's contingent fee agreement which was dated December 13, 2011. Also appended was a printout from the firm's computer database

showing that Ms. Smith was scheduled to undergo an echocardiogram at 9:00 a.m. on December 13, 2001.

Following Ms. Smith's submission of this evidence, counsel for the Trust, Harvey Sernovitz, Esq., informed Ms. Smith's counsel in an e-mail dated November 7, 2011 that Ms. Smith's claim would not be presented for audit until it was complete. It was the view of the Trust that since the December 2001 echocardiogram labeled the patient as "UNKNOWN," Ms. Smith had not submitted an echocardiogram of her heart which was necessary for audit of her claim. Two days after receiving Mr. Sernovitz's e-mail, Ms. Smith filed an appeal of the Trust's administrative determination. The issue as to whether the claim of Ms. Smith was ripe for appeal and for audit was referred to arbitration pursuant to §§ VI.C.4.h and VI.C.4.i of the Settlement Agreement.

In a Report and Award dated September 23, 2014, the Arbitrator disagreed with the Trust's contention that the appeal was premature. She determined that the Trust had issued a Final Determination denying Ms. Smith's claim.

However, the Arbitrator determined that the Trust's decision not to proceed with an audit of Ms. Smith's claim was not clearly erroneous. In the Arbitrator's view, the declarations of Drs. Muttreja and Dlabal and the affidavit of Ms. Kerr were insufficient to prove that the December 2001



echocardiogram showed Ms. Smith's heart. The Arbitrator explained that "[w]ith no information establishing the scientific or medical validity of" the cardiologists' conclusions, she had "no basis to credit them." Ultimately, she held that Ms. Smith "ha[d] not carried the burden of establishing that her Claim for Matrix Benefits [was] supported by a timely echocardiogram of her heart." Thus, according to the Arbitrator, Ms. Smith was not entitled to Matrix Benefits. If the Arbitrator is correct that Ms. Smith has not established it was her heart imaged in the echocardiogram, the supporting documentation for Ms. Smith's claim was obviously not complete.

Ms. Smith has now appealed the Arbitrator's decision to this court as permitted under the Settlement Agreement. See Settlement Agreement § VI.C.4.i. We apply a clearly erroneous standard of review to the Arbitrator's findings of fact and conduct a plenary review of conclusions of law. First Options of Chicago, Inc. v. Kaplan, 514 U.S. 938, 947-49 (1995). The ruling of this court, as previously noted, is final and binding. See Settlement Agreement § VI.C.4.1.

We agree with the first determination made by the Arbitrator that this matter is properly the subject of an appeal. Pursuant to the Audit Rules, the Trust "shall refer to Audit all Claims that have been completed in accordance with the terms of § VI.C of the Settlement Agreement." Audit Rule 3.

Section VI.C of the Settlement agreement, in turn, requires - among other things - that a claimant submit a videotape or disk reflecting the results of any echocardiogram on which her claim relies. Settlement Agreement § VI.C.2.f. The Audit Rules further provide that "all Claims for Matrix Compensation Benefits denied by the Trust without Audit, including without limitation those denied as incomplete or on the ground that the Green Form as completed does not establish a Matrix-Level condition, shall be heard pursuant to an appeal and arbitration." Audit Rule 18(e). The Trust's e-mail informing Ms. Smith's counsel that her claim would not be referred to audit until it was complete constituted a denial, which triggered the right to appeal under Audit Rule 18(e).

We now turn to the second determination of the Arbitrator, that is, her conclusion that the Trust did not err in refusing to refer Ms. Smith's claim to audit and that Ms. Smith was not entitled to Matrix Benefits. The Arbitrator did not discuss the proper standard of proof for a showing by a Matrix Benefits claimant that the heart depicted in the echocardiogram submitted in support of her claim was her own. Instead, the Arbitrator reviewed the evidence relied upon by Ms. Smith to show that the December 2001 echocardiogram imaged her heart. She then reasoned that without information about "the

scientific or medical validity of" the conclusions of Drs. Muttreja and Dlabal she would not credit their declarations.

Ms. Smith maintains that her claim is complete and thus ready for audit because there is sufficient credible evidence that the December 2001 echocardiogram is hers. Section VI.C.4.a of the Settlement Agreement sets forth the documentation that a claimant must submit along with a Green Form in support of a claim for Matrix Benefits. Pursuant to that section, a claimant is required to submit - among other things - "a copy of the videotape or disk of the Echocardiogram results which, in whole or in part, forms the basis for the Claim for Matrix Compensation Benefits." Settlement Agreement § VI.C.4.a(2). After a claim is complete - meaning that the claimant has submitted to the Trust the materials described in § VI.C.4.a together with a Green Form signed by an attesting physician - the trust must submit the claim to audit. Audit Rule 3. Once the claim proceeds to audit, it is the responsibility of the auditing cardiologist to determine "whether or not there was a reasonable medical basis for the representations made by any physician in support of the Claim." Settlement Agreement § VI.E.6.

Ms. Smith has met her burden of showing that the December 2001 echocardiogram submitted in support of her Green Forms depicts her heart. The uncontradicted declaration of Dr.

Muttreja states that the December 2001 echocardiogram is Ms. Smith's to a reasonable medical certainty. See Griffin v. Univ. of Pittsburgh Med. Ctr., 950 A.2d 996, 1000 (Pa. Super. Ct. 2008).<sup>6</sup> It is the "totality and substance" of an expert's opinion that matters, not his use of any "so-called 'magic words.'" Id. at 1003. Dr. Muttreja's later statements supplemented but did not qualify or replace his conclusion that there was a "reasonable medical certainty" that the heart depicted in the December 2001 echocardiogram was Ms. Smith's.

The additional evidence submitted by Ms. Smith reinforces her proof that the heart shown in the December 2001 echocardiogram is her own. Dr. Dlabal asserted in his declaration that the December 2001 echocardiogram and an echocardiogram confirmed to be that of Ms. Smith's heart "were performed on the same person" and that his opinion was "based on a reasonable medical certainty." As such, the "substance and totality" of Dr. Dlabal's assertions lend support to the conclusion that, to a reasonable degree of medical certainty, the December 2001 echocardiogram is Ms. Smith's. See Griffin, 950 A.2d at 1003.

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6. The "reasonable degree of medical certainty" requirement articulated in Griffin is a substantive one constituting part of a plaintiff's burden of proof, and consequently applies in federal court. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 750-52 (3d Cir. 1994); see also Valido-Shade v. Wyeth LLC, -- F. Supp. 3d --, No. 12-20003 at \*2 (E.D. Pa. Nov. 3, 2014).

Finally, Ms. Kerr's declaration and the accompanying materials, while circumstantial, further underscore Ms. Smith's proof that the echocardiogram in issue shows her heart. The Trust, we note, has come forward with no evidence disputing what Ms. Smith has presented. In sum, the declarations of Drs. Dlabal and Muttreja and the materials provided by Ms. Kerr persuade us that the heart shown in the December 2001 echocardiogram is Ms. Smith's to a reasonable degree of medical certainty.

Our current task is not to determine whether Ms. Smith is entitled to Matrix Benefits. We must simply assess whether it was clear error for the Arbitrator to conclude that the Trust did not clearly err in denying Ms. Smith's claim as incomplete. See First Options of Chicago, Inc., 514 U.S. at 947-49; Arbitration Rule 5. Based on the undisputed evidence presented by Ms. Smith, the Arbitrator committed clear error in affirming the Trust's denial of Ms. Smith's claim as incomplete. There is no basis for the Arbitrator's pronouncement that the opinions of Drs. Muttreja and Dlabal "are but bald assertions of comparative conclusions." To the contrary, without a shred of contradictory evidence provided by the Trust or any basis to deny the credibility of Drs. Muttreja and Dlabal, the materials tendered by Ms. Smith are more than adequate to support her claim that

the December 2001 echocardiogram is her own. Her claim is therefore complete and must be permitted to proceed to audit.

The Report and Award of the Arbitrator will be affirmed in part and reversed in part. The Arbitrator's finding and conclusion that the Trust's November 7, 2001 e-mail constituted a denial of Ms. Smith's claim for Matrix Benefits will be affirmed. The findings and conclusions of the Arbitrator will otherwise be reversed, and the matter is remanded to the Trust to conduct the appropriate audit based upon the December 2001 echocardiogram and other documentation submitted by Ms. Smith.